

REMARKS

Claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-78 and 98, 99 and 101 are presently pending in the case. Claims 97 and 100 have been cancelled without prejudice or disclaimer, Applicant reserving the right to pursue the claims in a continuation or divisional application. Claims 1, 23, 63, 98, 99 and 101 have been amended. The amendments are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under judicially created doctrine of Double Patenting

The Examiner provisionally rejected claims 1-15, 18-20, 23-25, 28-31, 38-40 and 98-100 under the judicially created doctrine of double patenting as being unpatentable over claims 23-25, 27-30, 35-44 of U.S. Patent Application Serial No. 11/187,757 in view of U.S. Patent 6,395,300 to Straub et al (hereinafter Straub et al) and U.S. Patent 4,950,477 to Schmidt et al (hereinafter Schmidt et al).

Since the claims have not been indicated as being otherwise in condition for allowance, a response to the Double Patenting rejection at this time would be premature. Therefore, the Applicant is holding such response in abeyance until such time as the claims are indicated allowable but for the Double Patenting issue.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-76 and 98-101 under 35 USC §103(a) as being unpatentable over U.S. Patent 6,207,703 to Ponikau (hereinafter Ponikau) in view of U.S. Patent 6,395,300 to Straub et al (hereinafter Straub et al). The rejection is traversed.

Ponikau and Staub et al do not render claim 1 unpatentable. Claim 1 is to a method of providing therapy against a pulmonary fungal infection comprising determining a minimum inhibitory concentration of an antifungal agent for inhibiting a specific pulmonary fungal infection and administering by inhalation directly to the lungs of a patient a powder aerosolized pharmaceutical formulation comprising an antifungal agent having efficacy against said pulmonary fungal infection, wherein the powder comprises porous particles and has a mass median aerodynamic diameter of less than about 5 microns and a bulk density of less than about 0.5 g/cm³, the powder formulation being administered in a first dosage, followed after a predetermined time interval by a second dosage, said first dosage being greater than the second dosage, wherein a sufficient amount of the pharmaceutical formulation is administered to maintain for at least one week a target antifungal lung concentration of at least two times the determined minimum inhibitory concentration. Ponikau and Staub et al do not teach or suggest all of these features and do not render claim 1 unpatentable.

First, Ponikau teaches the treatment of non-invasive, fungus-induced mucositis and does not teach treating a pulmonary fungal infection. As discussed in column 13 lines 18-25 of Ponikau, a non-invasive fungus-induced mucositis is an inflammation, not an infection. As further pointed out by Ponikau, "inflammations are fundamentally and clinically different from infections" (column 13 lines 20-21). Thus, Ponikau does not teach the treatment of a fungal infection, as claimed by Applicant. Further, claim 1 recites more than the mere treatment of a fungal infection. Also positively recited is the step of determining the minimum inhibitory concentration of an antifungal agent for inhibiting a specific pulmonary fungal infection. Since Ponikau does not teach the treatment of a fungal infection, it clearly does not teach the determination of a minimum inhibitory concentration of an antifungal agent for inhibiting the fungal infection. It also fails to teach the administration of a sufficient amount of the pharmaceutical formulation to maintain for at least one week a target antifungal lung concentration of at least two times the determined minimum inhibitory concentration. Staub et al is not relied upon to make up for these deficiencies, nor does it. Accordingly, the Examiner has not

established a *prima facie* case under 35 U.S.C. §103(a) and the rejection of independent claim 1 is improper.

Furthermore, Ponikau lacks a teaching of addition features positively recited in claim 1. For example, claim 1 recites the administration by inhalation directly to the lungs of a patient a powder aerosolized pharmaceutical formulation comprising an antifungal agent having efficacy against said pulmonary fungal infection, wherein the powder comprises porous particles and has a mass median aerodynamic diameter of less than about 5 microns and a bulk density of less than about 0.5 g/cm³. Ponikau does not teach this administration. Moreover, Ponikau does not teach such administration in a first dosage, followed after a predetermined time interval by a second dosage, said first dosage being greater than the second dosage. The Examiner attempts to make up for these deficiencies by relying on the teachings of Straub et al. However, whatever the teachings of Straub et al are in this regard, they have been mischaracterized by the Examiner. One of ordinary skill in the art would not have combined Ponikau and Straub et al in a manner that would have arrived at the invention claimed by Applicant in claim 1.

For at least these reasons, claim 1 is not properly rejectable under 35 USC §103(a) as being unpatentable over Ponikau and Straub et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Straub et al could be applied, with a reasonable likelihood of success, to Ponikau. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 1, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 1 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 2-15, 18-20 and 98 which depend from claim 1 and are not rendered unpatentable by Ponikau and Straub et al for at least the same reasons as claim 1.

Ponikau and Straub et al do not render independent claim 23 unpatentable either. Claim 23 is to a method of providing therapy against a pulmonary fungal infection comprising an aspergillosis, the method comprising administering by inhalation directly to the lungs of a patient an aerosolized pharmaceutical formulation comprising amphotericin B, wherein the formulation comprises porous particles characterized by a mass median aerodynamic diameter of less than about 5 microns and a bulk density of less than about 0.5 g/cm³, and wherein a sufficient amount of the pharmaceutical formulation is administered to maintain for at least two weeks a target amphotericin lung concentration of at least 9 µg/g, and wherein the administration comprises a first administration period and a second administration period and wherein the amphotericin B is administered more frequently or at a higher dosage during the first administration period than during the second administration period. Ponikau does not teach or suggest the treatment of a pulmonary infection in the manner recited. Straub et al does not make up for the deficiencies of Ponikau. Thus, Ponikau and Staub et al do not render claim 23 unpatentable.

For at least these reasons, claim 23 is not properly rejectable under 35 USC §103(a) as being unpatentable over Ponikau and Straub et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Straub et al could be applied, with a reasonable likelihood of success, to Ponikau. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 23, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 23 is

allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 23 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 24, 25, 28-31, 38-40 and 101, which depend from claim 23 and are not rendered unpatentable by Ponikau and Straub et al for at least the same reasons as claim 23.

Ponikau and Straub et al also do not render independent claim 63 unpatentable either. Claim 63 is to a method of providing therapy against a pulmonary lung infection, the method comprising determining the minimum inhibitory concentration of an antifungal agent for inhibiting at least one specific pulmonary fungal infection; administering an aerosolized pharmaceutical formulation comprising the antifungal agent by inhalation directly to the lungs of a patient, wherein the amount of the pharmaceutical formulation administered is sufficient to achieve a target antifungal agent lung concentration that is greater than the determined minimum inhibitory concentration; thereafter administering an immunosuppressive agent to the patient for a period of time; and maintaining the target antifungal agent lung concentration throughout the period of time. The combination of these features is not taught by Ponikau. Straub et al does not make up for the deficiencies.

For at least these reasons, claim 63 is not properly rejectable under 35 USC §103(a) as being unpatentable over Ponikau and Straub et al. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Straub et al could be applied, with a reasonable likelihood of success, to Ponikau. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 23, and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 63 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 63 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 64-76 and 99 which depend from claim 63 and are not rendered unpatentable by Ponikau and Straub et al for at least the same reasons as claim 63.

The Examiner rejected claims 77 and 78 under 35 USC §103(a) as being unpatentable over Ponikau and Straub et al and further in view of U.S. Patent 5,854,280 to Gomez et al (hereinafter Gomez et al). Claims 77 and 78 depend from claim 63. Claim 63 is not rendered unpatentable by Ponikau and Straub et al, as discussed above. Gomez et al does not make up for the deficiencies of Ponikau and Straub et al in rejecting claim 63. Thus, claim 63 is patentable over Ponikau, Straub et al and Gomez et al. Dependent claims 77 and 78 are also allowable over the references for at least the same reason as the claim from which they depend.

Conclusion

The claims are allowable for the reasons given above. Therefore, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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By: 
Guy V. Tucker
Reg. No. 45,302

Guy Tucker
Janah & Associates
650 Delancey Street, Suite 106
San Francisco, CA 94107
Phone: (415) 538-1555
Fax: (415) 538-8380